

**Remarks/Arguments**

Claims 1-20 are pending in the subject application. Claims 15 and 16 are cancelled herein. Accordingly, claims 1-14 and 17-20 are presented for examination on the merits.

Claim 1 has been amended to incorporate the limitations of claims 15 and 16. Amendments to other pending claims are formal in nature. Accordingly, the amendments to the claims do not add new matter. It is respectfully submitted that the claim amendments place the application in condition for allowance and therefore, should be entered.

**I. Rejection of Claims Under 35 U.S.C. § 102(b) Over Thatcher**

Claims 1, 2, 11-15, 17, 19 and 20 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Thatcher et al. The Examiner maintains that all of the limitations of the claimed invention are disclosed in the cited prior art.

It is respectfully submitted that the amendments to claim 1 render this ground of rejection moot.

Accordingly, the rejection of claims under 35 U.S.C. § 102(b) over Thatcher et al. is respectfully traversed.

**II. Rejection of Claims Under 35 U.S.C. § 102(b) Over Aberin**

Claims 1-14 and 17-20 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Aberin. The Examiner maintains that all of the limitations of the claimed invention are disclosed in the cited prior art.

It is respectfully submitted that the amendments to claim 1 render this ground of rejection moot.

Accordingly, the rejection of claims under 35 U.S.C. § 102(b) over Thatcher et al. is respectfully traversed.

### **III. Rejection of Claim 16 Under 35 U.S.C. § 103(a)**

It is respectfully submitted that cancellation of claim 16 renders this ground of rejection moot.

### **IV. Non-Obviousness of the Claimed Invention**

The present invention is directed to an improved chromatographic method of purifying plasmid DNA from a sample containing a mixture of nucleic acids, such as a cell extract, that does not require the use of RNase to eliminate from RNA and other nucleic acid species from the sample. Applicants have discovered that use of a silanized chromatographic stationary phase is sufficient to separate the RNA and single stranded DNA from plasmid DNA so that each elutes as a well separated chromatographic peak. Use of the silanized stationary phase in the present invention eliminates RNA from the sample without the need to denature the RNA first, using RNase for example, which is expensive and requires care in its application to avoid contamination of other equipment with the RNase. Thus, the present invention offers a significant improvement over the cited prior art methods for purifying plasmid DNA.

In contrast, Thatcher discloses a chromatographic method that relies on denaturation of nucleic acids and the preferred addition of RNase to eliminate the contaminating nucleic acids. Thatcher et al. teach that residual denatured nucleic acid can be eliminated *via* anionic exchange chromatography. However, Thatcher et al., do not disclose or suggest that chromatography alone is sufficient to remove the contaminating nucleic acids. In particular, Thatcher et al. do not disclose or suggest that silanization of the chromatographic stationary phase eliminates the need to denature the nucleic acids through the use RNase to achieve purity of plasmid DNA.

Colpan merely discloses the silanized matrix for chromatographic purification of plasmid DNA, but does not disclose or suggest that the silanized matrix eliminates the need to denature

nucleic acids in order to obtain sufficient separation of plasmid DNA and RNA. That result was the unexpected discovery of Applicants and was neither suggested nor disclosed in the cited prior art. Thatcher et al. teaches a methodology that relies on nucleic acid denaturation. Thus, even if one of skill in the art were motivated to use Colpan's matrix in Thatcher's method, the skilled practitioner would not have known from the disclosure of these prior art patents that the denaturation step would not be necessary. The results of such combination are clearly unexpected in view of the teachings of the prior art.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



Judith Toffenetti  
Registration No. 39,048

600 13<sup>th</sup> Street, N.W.  
Washington, DC 20005-3096  
Phone: 202.756.8000 JLT:ASA:apr  
Facsimile: 202.756.8087  
**Date: July 6, 2009**  
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